

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR
SYSTEMS PRODUCTS LIABILITY
LITIGATION

Master File No. 2:12-MD-02327
MDL 2327

ETHICON WAVE 8 CASES LISTED IN
EXHIBIT A TO PLAINTIFFS' MOTION

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

**DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION TO
PRECLUDE OR LIMIT OPINIONS OF EXPERT C. BRYCE BOWLING [DKT. 6876]**

Defendants submit this opposition in response to Plaintiffs' Motion to Preclude or Limit Opinions of Defense Expert C. Bryce Bowling. Plaintiffs do not challenge the qualifications of Dr. Bowling, a urogynecologist and board-certified pelvic floor reconstruction surgeon with over 15 years of experience. Ex. B Wave 8 Bowling Rpt. (Prolift, Prolift M+ and Gynemesh) at 1-2.¹ Plaintiffs' challenges to the reliability of Dr. Bowling's opinions should be denied for the following reasons:

I. Dr. Bowling Will Not Offer Opinions Drawing Legal Conclusions.

Defendants acknowledge that this Court has previously held that an expert may not state his opinion using legal terms of art, *Ramsey v. Boston Sci. Corp.*, No. 2:13-cv-15223, 2016 WL 2939526, at *2 (S.D.W. Va. May 19, 2016), nor may he opine that a particular warning label "adequately inform[s] users of the dangers associated with using the device." *Hall v. Boston Scientific Corp.*, No. 2:12-CV-08186, 2015 WL 868907, at *10 (S.D.W. Va. Feb. 27, 2015). Accordingly, Dr. Bowling will not offer the opinion that the IFUs in issue "adequately" warned of potential complications. Rather, Dr. Bowling will opine regarding which risks exist (or do not

¹ Unless otherwise noted, all exhibit references are to exhibits attached to Plaintiffs' motion to exclude.

exist) associated with the products in issue, whether these risks were identified in the IFUs or were otherwise generally known to pelvic floor surgeons.

According to the FDA regulations governing warnings, a product IFU need not warn of risks that are known generally to the users of products. The FDA device regulations say that information may be omitted from labeling:

if, but only if, the article is a device for which directions, hazards, warnings and other information are **commonly known to practitioners licensed by law to use the device**.

21 C.F.R. §801.10(c) (emphasis added); *see also Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230 (4th Cir. 1984) (duty to warn only of dangers “not well known to the medical community.”).

Because of this legal standard, Ethicon is entitled to defend the adequacy and contents of its warnings by referencing what licensed surgeons would know about the risks associated with pelvic floor surgery, including surgery using mesh augmentation. Since Ethicon’s warnings are not to be judged by just what one particular surgeon knew, but by what commonly would be known to such physicians generally, Ethicon’s experts can reference the common knowledge of surgeons in offering opinions concerning Ethicon’s warnings. *See Waterhouse v. R.J. Reynolds Tobacco Co.*, 368 F. Supp. 2d 432, 437 (D. Md. 2005), *aff’d*, 162 F. App’x 231 (4th Cir. 2006) (“expert testimony is required with respect to the state of common knowledge of smoking hazards during the smoking career of a plaintiff and that that testimony must be rendered by competent experts.”); *Cruz-Vargas v. R.J. Reynolds Tobacco Co.*, 348 F.3d 271, 277 (1st Cir. 2003) (testimony regarding common knowledge is critical in failure to warn cases, and expert opinion concerning knowledge of average consumer was appropriate and relevant).

As noted by this Court, “doctors are fully qualified to opine on the medical facts and science regarding the risks and benefits of drugs and to compare that knowledge with what was

provided in the text of labeling and warnings.” *Winebarger v. Boston Scientific Corp.*, No. 2:13-CV-28892, 2015 WL 1887222, at *15 (S.D.W. Va. Apr. 24, 2015) (quoting *In re Yasmin & Yaz (Drospirenone) Prods. Liab. Litig.*, No. 3:09-md-02100, 2011 WL 6301625, at *11 (S.D. Ill. Dec.16, 2011)).

Because Ethicon agrees that Dr. Bowling will not offer opinions drawing ultimate legal conclusions, Plaintiffs’ motion should be denied as moot.

II. Dr. Bowling’s Opinions are Properly Supported and Reliable

Plaintiffs argue that Dr. Bowling’s opinions should be excluded “to the extent” he “relied” on case specific expert opinions from other cases, statements by Plaintiff’s counsel, and other sources “he cannot attribute.” Plf. Mem. at 5.

Plaintiffs’ objections largely relate to testimony that was solicited by Plaintiffs’ counsel at Dr. Bowling’s deposition and taken out of context for Plaintiffs’ motion. For instance, Plaintiffs object to Dr. Bowling’s opinions to the extent that he relied on “individual case specific opinions.” *Id.* Yet, Dr. Bowling is a designated case-specific expert in twenty-two Wave 8 cases.² Consequently, Dr. Bowling reviewed other expert reports related to those cases. In the spirit of full disclosure, he noted this fact in his in his general expert report. Ex. C Bowling Rpt. (Gynecare TVT/TVT Exact/TVT-O) at 5; Ex. 1, attached hereto, Reliance List at 21-22. When

² *Booth v. Ethicon, Inc. et al*, No. 2:17-CV-03958; *Bushway et al v. Ethicon, Inc. et al*, No. 2:16-CV-08070, *Hill et al v. Ethicon, Inc. et al*, No. 2:13-CV-33413; *Morales v. Ethicon, Inc. et al*, No. 2:17-CV-03029; *Nunn et al v. Ethicon, Inc. et al*, No. 2:15-CV-03265; *Roberson et al v. Ethicon, Inc. et al*, No. 2:15-CV-03277; *Smith et al v. Ethicon, Inc. et al*, No. 2:15-CV-13745; *Wheat v. Johnson & Johnson et al*, No. 2:15-CV-01889; *Brown v. Ethicon, Inc. et al*, No. 2:17-CV-03869; *Carpenter v. Ethicon, Inc. et al*, No. 2:16-CV-10078; *Copley v. Ethicon, Inc. et al*, No. 2:16-CV-09651, *Crosswhite et al v. Ethicon, Inc. et al*, No. 2:15-CV-13394; *Davis et al v. Ethicon, Inc. et al*, No. 2:15-CV-13898; *Howard v. Ethicon, Inc. et al*, No. 12-CV-06539; *Kendall v. Ethicon, Inc. et al*, No. 2:15-CV-15778, *McDaniel et al v. Ethicon, Inc. et al*, No. 2:15-CV-13301; *Norman v. Ethicon, Inc. et al*, No. 2:15-CV-16388; *Patterson v. Ethicon, Inc. et al*, No. 2:14-CV-17584; *Serna et al v. American Medical Systems, Inc.*, No. 2:16-CV-10209; *Sullivan et al v. Ethicon, Inc. et al*, No. 2:15-CV-16394; *Thompson et al v. Ethicon, Inc. et al*, No. 2:15-CV-02652; and *Wyatt v. Ethicon, Inc. et al*, No. 2:18-CV-00033.

questioned at his deposition, Dr. Bowling explained “I looked over expert opinions in both general reports and case specific reports for several of the cases that I was working on to see what the plaintiff’s claims were regarding midurethral slings.” Ex. 2, attached hereto, Bowling Dep. at 45:10-46:1.

As a designated general and case-specific expert in Wave 8, it is expected, indeed, required that Dr. Bowling would review relevant general and case-specific expert reports submitted by Plaintiffs’ experts. Dr. Bowling has not proposed testifying about individual plaintiffs within his general causation reports or during general causation testimony. Rather, he has merely disclosed that these reports were included in the materials he reviewed in forming his opinions. It is unclear what Plaintiffs’ counsel finds objectionable about this practice, which perhaps explains the failure to support this argument with any legal citation.

Similarly, Plaintiffs’ objection to Dr. Bowling’s reference to “Plaintiffs’ counsel’s” claims and “assurances” is nothing but a semantics game. At times in Dr. Bowling’s reports, he referred to the allegations made in this litigation by characterizing such claims as “assurances from Plaintiff’s Counsel”, “suggestions by Plaintiff’s counsel”, or “Plaintiff’s counsel claims.” Ex. B at 14 & 39; Ex. C at 16 & 18. It is clear from the context of these statements, the remainder of his expert reports, and his deposition testimony, that these references are to the MDL plaintiffs’ claims—not, as Plaintiffs’ motion suggests, statements by any specific plaintiff’s counsel. *See, e.g.*, Ex. B Bowling Rpt. at 39 (“Any suggestions by Plaintiff’s counsel regarding ‘mesh degradation’ are also not supported by reasonable medical literature.”); *Id.* (“There is no clinical evidence supporting plaintiff’s counsel claims that a lighter weight, larger pore, partially absorbable mesh would be a safer alternative design.”).

When allowed to explain at his deposition, Dr. Bowling clarified what his sources were when defining “Plaintiff’s counsel’s” claims: “If you go through plaintiffs' experts' reports, I think it will be abundantly clear what I'm saying here” Ex. 2, attached hereto, Bowling Dep. at 203:24-204:3; See also *Id.* at 204:1-16 (“What I will say is that in the reports, the general reports as well as the case specific reports that I have reviewed, that I have seen multiple experts make claims, unsubstantiated claims of cytotoxicity, chronic inflammation, degradation and everything else that I have listed here. So while I have not named them, rest assured that if I have made a claim that plaintiffs' experts have made claims in their statements it has been something that I have seen.”).

Dr. Bowling included in his reliance list the plaintiffs’ expert reports that he reviewed to identify the relevant claims. Ex. 1, attached hereto, Reliance List at 21-22; *See also* Ex. 2, attached hereto, Bowling Dep. at 206:2-207:22 (Defense counsel objecting to Plaintiffs’ counsel’s line of questioning on this issue: “. . . that information is found in great detail on his reliance list for the specific expert reports that he has been sent and reviewed are itemized.”)

Upon additional question, Dr. Bowling made his statements even clearer:

Q [Plaintiffs’ Counsel]: Your number two, your number three, your number four, five and six all begin with the same phrases, plaintiffs' expert/counsels' and then proceed with the statement that you would attribute to them. Again, you're not going to name –

A. It's not a statement that I'm attributing to them. It's statements that they have made in their reports.

Q. Okay. Counsels' report?

A. No, plaintiffs' experts' report.

Ex. 2, attached hereto, Bowling Dep. at 212:10-23.³ Further, although Plaintiffs’ counsel elicited testimony regarding actual statements by other plaintiff’s counsel, Dr. Bowling does not intend

³ See also, Ex. 2, Bowling Dep. at 231:3-13:

to refer to statements by individual counsel, and will be instructed to reference the MDL plaintiffs' claims rather than the claims of "plaintiffs' counsel."

Dr. Bowling has adequately supported his opinions regarding the safety and efficacy of the Ethicon products in issue with reliable, verifiable materials. He relied on well over 200 relevant scientific publications, performed independent research, reviewed numerous Ethicon documents and expert depositions, and relied on his extensive experience as a pelvic floor surgeon. Ex. B Bowling Rpt. (Gynemesh/Prolift); Ex. C Bowling Rpt. (TVT); Ex. 1, attached, Reliance List.

For these reasons, the Court should reject Plaintiffs' argument.

III. Dr. Bowling Is Allowed to Rely on Materials Provided by Counsel, His Own Clinical Experience, and To Disagree with FDA Statements.

Plaintiffs seek to exclude Dr. Bowling's testimony because "his opinions were based on his anecdotal personal experience and . . . much of the data he reviewed was selectively provided to him by Defendant's counsel." Plf. Mem. at 7. Plaintiffs' complaints are inaccurate and provide no basis for excluding expert testimony. Dr. Bowling relied not only on his personal professional experiences and materials provided by counsel, but also his own research and material he requested be added to his reliance list:

A: The reliance list has been put together by Butler Snow. It is a culmination of materials that they provided to me that I requested and that I researched on my own and cited in my report.

Ex. 2, attached hereto, Bowling Dep. at 76:19-23; Ex. 1, Reliance List. As confirmed in his deposition, in preparing his reports, Dr. Bowling performed an independent systematic review of relevant articles. Ex. 2, Bowling Dep. at 67:1-15; Ex. B Bowling Rpt. at 5 ("I have performed

Q. And when you say plaintiffs' expert/counsel, is that your way of communicating the overall position of the plaintiffs in this litigation is fill in the blank?

MS. GAYLE: Objection, leading and form.

THE WITNESS: Yes, it is. It is again a culmination of different experts as I stated earlier in her questioning. This is a culmination of expert witnesses that have provided both general and case specific testimony and I have used their claims in my report.

an exhaustive study of the scientific literature including Cochran reviews, randomized controlled trials (RCTs), and peer-reviewed research studies . . . “). He also performed a review of Ethicon’s surgeon resource monograph, professional materials, the relevant product IFUs and other company documents. Ex. B at 5; Ex. 1, Reliance List.

Additionally, Dr. Bowling has extensive experience in pelvic floor surgery and implanting the Ethicon products in issue, which he is allowed to rely upon in forming his opinions. *See* Ex. 3, attached hereto, Bowling CV; *Carlson v. Boston Scientific Corp.*, No. 2:13-CV-05475, 2015 WL 1931311, at *12, *36 (S.D.W. Va. Apr. 28, 2015) (finding Dr. Galloway’s method of considering scientific articles and drawing on his clinical experience to reach his opinion regarding degradation to be methodologically sound and allowing Dr. Culligan “by way of his experience with the Uphold device and his review of the relevant scientific literature” to opine how these procedures compare).

Dr. Bowling is Board Certified in both Obstetrics & Gynecology and Female Pelvic Medicine & Reconstructive Surgery. Ex. B Bowling Rpt. at 2. He currently serves as Director for the Division of Female Pelvic Medicine and Reconstructive Surgery at The University of Tennessee Medical Center. *Id.* at 3. He has performed thousands of pelvic floor reconstructive procedures to treat and cure pelvic organ prolapse both with and without the use of mesh. *Id.* Dr. Bowling has trained with and performed the Gynecare TVT procedures since 2004 and has successfully completed over 2000 retropubic sling procedures. *Id.* at 4. He has performed hundreds of transobturator slings. *Id.* He has also trained with and performed the Gynecare Prolift procedure in excess of 500 times (Anterior, Posterior, and Total). *Id.* As demonstrated, Dr. Bowling relied on this experience, *in addition to* his independent research, additional materials provided by counsel, Ethicon documents, and various other materials.

In *Mathison v. Boston Scientific Corporation*, this Court found that a board-certified urologist, Dr. Lonny S. Green, who had conducted nearly 3,000 sling procedures and practiced for twenty years was qualified to opine that the mesh product does not shrink, contract, degrade, or cause systemic infections. No. 2:13-CV-05851, 2015 U.S. Dist. LEXIS 59047, at *27-28 (S.D.W. Va. May 6, 2015). The Court further found that the doctor's clinical experience and review of scientific literature were sufficiently reliable bases in forming the opinion. *Id.* at *27.⁴ Like Dr. Green, Dr. Bowling has sufficient familiarity and experience with sling procedures, mesh slings generally, pelvic floor prolapse procedures, and the Gynemesh, TVT and Prolift devices in particular to provide reliable opinions on whether they are safe and effective, and whether they shrink, contract, or degrade. He did not, as Plaintiffs' suggest, "solely rely on personal observations" Plf. Mem. at 9.

Plaintiffs also seek to exclude Dr. Bowling's opinions because he did not "consider a number of peer review articles that found mesh complications" and his conclusions allegedly "conflict with the FDA's advisories." Plf. Mem. at 9. The fact that he disagrees or criticizes FDA statements to the contrary, and has explained why he disagrees, does not impact the admissibility of his opinions. Ex. 2, Bowling Dep. at 129:1-146:6 (explaining in detail why he disagrees with certain FDA statements and studies). Additionally, "[i]f there are certain device-

⁴ See also, *In re C.R. Bard, Inc.*, 948 F. Supp. 2d 589, 612 (S.D.W. Va. 2013) (Goodwin, J.) (ruling that an expert was qualified to opine on product design and biomaterials because he had "extensive experience with pelvic floor disorders and the use of mesh to treat such disorders"); *In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2017 WL 988838, at *3 (S.D.W. Va. Mar. 10, 2017) (denying plaintiffs' motion to exclude testimony by board-certified obstetrician-gynecologist regarding the "safety and efficacy" of SUI and POP products); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures," and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Sci. Corp.*, No. 2:13-CV-04505, 2015 WL 2087048, at *24 (S.D.W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit.") .

specific publications that [the expert] failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.” *Ramsey*, 2016 WL 2939525 at *14; *see also id.* at *4 (S.D.W. Va. Apr. 28, 2016) (finding that “to the extent the defendant challenges the reasons Dr. Margolis offers for not relying on certain studies, such challenges go to the weight of Dr. Margolis’s opinions, not their admissibility” and that “[t]he defendant is free to cross-examine Dr. Margolis regarding studies that cut against his opinions”).

This Court has rejected similar challenges to defense expert urogynecologists. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691,735 (S.D.W. Va. 2014). Noting that the pelvic floor surgeon’s “clinical experience and his review of the scientific literature” set forth a sufficient basis for his opinion and his “failure to review particular documents goes to the weight of his opinion, not its admissibility.” *Id.*; *Trevino v. Boston Sci. Corp.*, No. 2:13-CV-01617, 2016 WL 2939521, at *40 (S.D.W. Va. May 19, 2016).

Plaintiffs’ citation to cases in which experts proposed to opine regarding personal complication rates without providing data to support those rates are inapposite. *See Frankum v. Boston Sci. Corp.*, No. 2:12-CV-00904, 2015 U.S. Dist. LEXIS 57251, at *24 (S.D.W. Va. May 1, 2015)(expert could not rely “solely” on personal observations when seeking to opine regarding infection rate in women with mesh); *Wise v. C.R. Bard Inc.*, No. 2:12-CV-01378, 2015 U.S. Dist. LEXIS 14869, at *25-26 (S.D.W. Va. Feb. 7, 2015)(“without a fully synthesized representation of [expert’s] database, specific reliance on that database is unreliable”). Dr. Bowling is not proposing to opine regarding his personal, specific complication rates or any unspecified or unidentified personal database—and Plaintiffs have not identified any such proposed testimony. Moreover, as this Court has recognized, *Daubert* does not require independent verification of “every single clinical experience [the physician] had over the course

of his career,” because otherwise, “the court would never make it past pre-trial motions.” *Bellew v. Ethicon, Inc.*, No. 2:13-CV-22473, Doc. 265, p. 40 (S.D.W. Va. Nov. 20, 2014); *see also Winebarger*, 2015 WL 1887222, at *34 (finding that expert’s lack of “exact statistics” about the outcome of his patients did not render his opinions based on personal experience unreliable and that “such detail is not required under Daubert to opine as to ‘large-scale safety and efficacy of the Uphold device’”); *Trevino*, 2016 WL 2939521, at *33 (same). *See, e.g., Tyree v. Boston Scientific Corp*, 54 F. Supp. 3d 501, 585 (S.D. W. Va. 2014) (expert’s opinion about safety and efficacy was reliable where opinion was based upon “minimal complications in his clinical practice” which was “‘on par with the findings of [the] studies’ he cites throughout his expert report”).

CONCLUSION

For the reasons stated above, the Court should deny Plaintiffs’ motion to exclude the opinions and testimony of Dr. Bryce Bowling.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this day, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ William M. Gage
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